UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION	C.A. No. 05-360 (KAJ) (consolidated)
THIS DOCUMENT RELATES TO: PAINTERS' DISTRICT COUNCIL NO. 30 HEALTH AND WELFARE FUND and RICHARD G. WILDE, C.A. No. 05-360 (KAJ) VISTA HEALTH PLAN, INC. and ROSS LOVE, C.A. No. 05-365 (KAJ) PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, C.A. No. 05-390 (KAJ) ALLIED SERVICES DIVISION WELFARE FUND and HECTOR VALDES, C.A. No. 05-394 (KAJ) DIANA KIM, C.A. No. 05-426 (KAJ) ELAINE M. PULLMAN, NEIL PERLMUTTER, HELENA PERLMUTTER and LULA RAMSEY, C.A. No. 05-450 (KAJ) PHILADELPHIA FEDERATION OF TEACHERS HEALTH AND WELFARE FUND, C.A. No. 05-467 (KAJ) CINDY CRONIN, C.A. No. 05 482 (KAJ) CHARLES SHAIN and SANDRA KRONE, C.A. No. 05-475 (KAJ) LOCAL 28 SHEET METAL WORKERS, C.A. No. 05-516 (KAJ) ALBERTO LITTER, C.A. No. 05-695 (KAJ)	

BRIEF IN SUPPORT OF INDIRECT PURCHASER PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

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Indirect Purchaser Plaintiffs ("End-Payor Plaintiffs" or "Plaintiffs") hereby submit this brief in support of their motion for class certification.

I. NATURE AND STAGE OF THE PROCEEDING

End-Payor Plaintiffs are consumers and third-party payors ("TPPs") who purchased, paid and/or reimbursed for fenofibrate products, including TriCor® ("TriCor") tablets and capsules.[1] TriCor is the brand name by which defendant Abbott Laboratories, Inc. ("Abbott") markets prescription drug products containing the cholesterol-lowering active pharmaceutical ingredient fenofibrate. To fend off generic competition and unlawfully maintain a monopoly in the market for fenofibrate products, Abbott and defendants Fournier Industrie et Sante and Laboratoires Fournier, S.A. (together, "Fournier" and collectively with Abbott, "Defendants") have employed a variety of tactics in executing an overall strategic scheme to make it impossible for generic competitors to market, or for consumers or TPPs to purchase or pay for, lower-cost generic fenofibrate products.

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End-Payor Plaintiffs seek injunctive relief under federal antitrust law (Count I) and monetary relief under state law (including that of the District of Columbia), *i.e.*, damages under 23 statutes that prohibit antitrust violations (commonly referred to collectively as the

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[1] The End-Payor Plaintiffs proffered as class representatives are consumers Cindy Cronin, Diana Kim, Sandra Krone, Alberto Litter, Neil and Helena Perlmutter, Elaine M. Pullman, Lula Ramsey, Charles M. Shain, Hector Valdes, and Richard G. Wilde, and TPPs Allied Services Division Welfare Fund, Sheet Metal Workers International Association Local Union 28, Painters' District Council No. 30 Health and Welfare Fund, Pennsylvania Employees Benefit Trust Fund, Philadelphia Federation of Teachers Health and Welfare Fund, and Vista Healthplan, Inc..

[2] Declaration of Christopher J. McDonald, dated May 8, 2006 ("McDonald Declaration") Exh. 29 (TRICOR000260-266, 261).

"Indirect Purchaser States") (Count II), restitution under unjust enrichment laws throughout the Country (Count III), and damages under consumer protection statutes in 43 jurisdictions (Counts IV and V).

Defendants' motions to dismiss the End-Payor Plaintiffs' Consolidated Class Action Complaint (the "End-Payor Complaint") [D.I. 24] and the claims of all other plaintiffs and counterclaim plaintiffs in the coordinated *Tricor Antitrust Litigation* are currently *sub judice*. Limited document discovery has transpired to date.[3] Although incomplete, the record is nevertheless sufficient to support certification of a putative class of end-payors (the "Class") who have been injured by virtue of their purchases of or payments for TriCor. *See* End-Payor Complaint [D.I. 24] ¶ 99, 102, 109. Like many other cases arising out of a brand-name drug manufacturer's suppression of generic competition (*see* note 30, *infra* (listing generic suppression cases among others)), Plaintiffs' claims are amenable to class-wide proof. By proving their own case, Plaintiffs will succeed in proving the claims of all absent Class members.

II. SUMMARY OF ARGUMENT

1. Rule 23 of the Federal Rules of Civil Procedure sets forth a two-part test for class certification: subsection (a) states the threshold requirements for all class actions; subsection (b) sets forth the three varieties of class actions contemplated by the Rule and the special requirements peculiar to each in addition to those of subsection (a). The Class

[3] Plaintiffs have received roughly 2 million pages of documents, most of which have been produced on CDs and DVDs. Within the last eight weeks alone, Plaintiffs have received over 20 disks, more than half of which were produced by Defendants. *See* McDonald Declaration ¶5.

represented by the End-Payor Plaintiffs may be certified because it satisfies the requirements of Rule 23(a), as well as those of Rules 23(b)(2) and (b)(3).

2. Plaintiffs meet Rule 23(a)'s requirements of numerosity, commonality, typicality, adequacy. *See In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231, 247 (D. Del. 2002) ("*Warfarin II*"), *aff'd*, 391 F.3d 516 (3d Cir. 2004) ("*Warfarin III*"). Section IV. A., *infra.*

3. Plaintiffs' federal antitrust claim for injunctive relief (Count I) can be certified under Rule 23(b)(2) because "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief necessary with respect to the class as a whole[.]" *See In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 402 (3d Cir. 2000) ("*Warfarin I*"); *see also In re New Motor Vehicles Canadian Export Antitrust Litig.*, MDL No. 1532, 2006 WL 623591 (D. Me. Mar. 10, 2006). Section IV. B., *infra.*

4. The Court should certify Plaintiffs' state law claims for damages and restitution (Counts II-V) under Rule 23(b)(3) because "questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and [] a class action is superior to other available methods for the fair and efficient adjudication of the controversy." *See In re Prudential Ins. Co. of Am. Sales Practices*, 962 F. Supp. 450 (D.N.J. 1997) ("*Prudential Sales Practices I*"), *aff'd*, 148 F.3d 283 (3d Cir. 1998) ("*Prudential Sales Practices II*"); *In re Pharmaceutical Industry Average Wholesale Price Litig.*, 230 F.R.D. 61 (D. Mass. 2005). Section IV.C., *infra.*

III. STATEMENT OF FACTS

A. The Role of Generic Drugs.

As described more fully in the End-Payor Complaint [D.I. 24] (*see* ¶¶ 26-47) and the accompanying report of Dr. Charles King III (the "King Report," *see* ¶¶ 23-28), generic drugs play a pivotal role in United States pharmaceutical markets:

> The Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act, reflects the intent of Congress to facilitate competition by generic drugs in the markets for prescription drugs. The Hatch-Waxman Act seeks to expand the availability of lower priced generic pharmaceutical products while preserving the incentive for pharmaceutical manufacturers to engage in research and development for new drugs. . . . By lowering barriers to entry for generic manufacturers, the Hatch-Waxman Act allows them to charge lower prices for their generic drugs and to capture larger market shares.

King Report ¶ 25 (footnote omitted).[4] "A generic drug is identical, or bioequivalent, to a brand name drug in safety, efficacy and therapeutic use. Although the active pharmaceutical ingredients of generic drugs are chemically identical to their branded counterparts, they typically sell at substantial discounts from the brand name price." King Report ¶ 23 (citation omitted). Generic drugs, and particularly AB-rated generic drugs, "provid[e] direct price competition to brand name drugs [and] are accorded special status by the federal government (particularly the FDA), state governments and private health plans, all of which promote the substitution of less expensive generic drugs for brand name drugs." *Id.* ¶ 24.

[4] End-Payor Plaintiffs have retained Dr. King, an economist specializing in microeconomics, industrial organizations, marketing and econometrics, as an expert witness in connection with their class certification motion. The King Report is annexed as Exhibit 1 to the McDonald Declaration. The documents produced in discovery that are cited in the King Report are annexed to the McDonald Declaration as Exhibits 2 through 28.

See also id. at ¶ 37 ("purchasers, including end payors, derive significant cost savings when AB-rated generic drugs in the market compete with their brand name counterparts") & n. 74 ("The FDA will assign an 'AB' therapeutic equivalence (TE) code to a drug that demonstrates 'adequate scientific evidence establishing...the bioequivalence of the product to a selectd reference listed drug'") (citing www.fda.gov/cder/drugsatfda/glossary.htm).

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B. Defendants Have Impeded Lawful Generic Competition.

End-Payor Plaintiffs allege, and the limited document discovery reviewed to date bears out, that Defendants have engaged in a scheme specifically designed to frustrate the balance struck by Congress with the Hatch-Waxman Act. The scheme has three main components: "product hopping," engaging in patent-related abuses, and manipulating the pharmaceutical distribution infrastructure. Through anticompetitive tactics and deception, Defendants have unlawfully maintained their monopoly on the U.S. fenofibrate market.

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[5] *See, e.g.*, McDonald Declaration Exh. 30: (ABBOTT TRICOR00086959-976, 962) (REDACTED

[6] McDonald Declaration Exh. 10: T REDACTED (ABBOTT_TRICOR00001197-1213, 1198); *see also* Exh. 9: REDACTED (ABBOTT_TRICOR00016561-650, 645) (REDACTED

Although Hatch-Waxman sought to preserve the incentive to develop *innovative* products, Abbott and Fournier found a lucrative alternative – devoting their research, marketing, regulatory, legal and other resources into simply tweaking existing TriCor formulations just enough to avoid having generic alternatives achieve an AB rating. Professor Hovenkamp has referred to this conduct as "product hopping":

> Product-hopping pharmaceutical companies faced with the possibility of generic competition once a patent expires or is held invalid sometimes make trivial alterations to their approved drugs, get FDA approval for those trivial alterations, and then replace the old product with the new. For example, a patentee might switch from selling a drug in capsule form to selling the same formulation of the same drug in tablet form. While the change won't matter much to consumers, it can be sufficient to require a generic company to start the ANDA filing process over from scratch, delaying the date of generic entry and triggering an entirely new round of patent litigation. Because the patented pharmaceutical is now being sold in the new tablet formulation, the generic company will be unable to rely on generic substitution to sell its ANDA-approved capsules.

Hovenkamp, Herbert, Janis, Mark D., Lemley, Mark A., *IP & Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, Vol. 1 § 12.5, at 12-45 (Aspen Pub. 2006 Supp.).

REDACTED

[7] Teva did not apply to the FDA for regulatory approval for a generic fenofibrate capsule until December

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[7] Abbott has also "product hopped" in the opposite direction – from tablets to capsules – to avoid generic competition for their pharmaceutical product Hytrin. REDACTED REDACTED McDonald Declaration Exh. 31 (FOURNIER/FTC0005517-540, 521).

1999.

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McDonald Declaration Exh. 32 (Fournier/FTC 0004449-454, 449) (emphasis in original).[8] Defendants have "product hopped" with TriCor twice, in September 2001, with a switch from capsules to 54mg and 160mg tablets, and again in 2005, with another switch to 48mg and 145mg tablets, which are sometimes referred to as "NFE" or "No Food Effect" tablets. End-Payor Complaint [D.I. 24] ¶¶ 53-59, 67-80.

[8] "Type II" refers to Types IIa and IIb of the Fredrickson classification system for dyslipidemia, which according to Abbott refers to "adults with high cholesterol, with or without elevated triglycerides." *See* http://tricortablets.com/patient/faqs.html (April 23, 2006).

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McDonald Declaration Exh. 31 (FOURNIER/FTC0005517-540, 533, 523) (emphasis added).

Defendants, of course, aggressively portrayed their product switches as improvements over their own and other fenofibrate formulations (such as generic equivalents of earlier versions of TriCor, and subsequently released brands Lofibra® ("Lofibra"), marketed by Teva Pharmaceuticals USA, Inc., and Antara™ ("Antara"), marketed by Reliant Pharmaceuticals, Inc.).

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[9] McDonald Declaration Exh. 33: **REDACTED** (ABBOTT_TRICOR00090958-984, 960).

[10] McDonald Declaration Exh. 34 (ABBOTT_TRICOR00084977). *See also* Exh. 35: **REDACTED** (ABBOTT_TRICOR0000739-764, 741) **REDACTED**

[11] McDonald Declaration Exh. 36 (ABBOTT_TRICOR00122165) (emphasis added).

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[12] McDonald Declaration Exh. 37: REDACTED
REDACTED (ABBOTT_TRICOR00001273-276, 275).

[13] McDonald Declaration Exh. 31 (FOURNIER/FTC0005517, 535). *See also* Exh. 35 at ABBOTT_TRICOR00000756 REDACTED

Exh. 38: REDACTED (ABBOTT_TRICOR00000007-062, 020)

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[14] McDonald Declaration Exh. 38 at ABBOTT_TRICOR000000018.

Defendants were able to achieve the favorable timetables they needed to launch their new versions of TriCor – and further their anticompetitive ends – by engaging in patent-related abuses. When generic manufacturers Teva and Impax Laboratories, Inc. sought to enter the market for fenofibrate products, their product launches were held up because Defendants launched patent infringement actions first. Those actions gave rise to mandatory delays of the FDA's authority to approve the generic fenofibrate applications.[15] The mandatory 30-Month Stays against the Teva and Impax ANDAs gave Defendants the time they needed to successfully "convert" the market to their new fenofibrate tablet formulations. **REDACTED**

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Plaintiffs further allege that Defendants were guilty of fraud before the U.S. Patent and Trademark Office ("PTO") and that certain of the patent infringement litigations launched against their generic competitors were shams.

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[15] Pursuant to the Hatch-Waxman Act, an Abbreviated New Drug Application ("ANDA") applicant making a Paragraph IV Certification is obligated to notify the owner of the listed patent of the filing of its ANDA and certification that the listed patent is either invalid or not infringed by its generic product (the "ANDA Notification"). 21 U.S.C. § 355(j)(2)(B). Thereafter, the patent holder has 45 days to initiate a patent infringement suit against the ANDA applicant. 21 U.S.C. § 355(j)(5)(B)(iii). If no infringement action is initiated within 45 days, the FDA may approve the ANDA at any time. *Id.* If a timely infringement suit is commenced, the FDA is forbidden from giving final approval to the ANDA until one of the following occurs: (1) the patent expires, (2) the expiration of 30 months from the ANDA Notification (the "30-Month Stay"), or (3) a final judicial determination of invalidity or non-infringement. 21 U.S.C. § 355(j)(5)(B)(iii).

[16] **REDACTED**

See, e.g., McDonald Declaration Exh. 39 (ABBOTT_TRICOR00000768-779, 770); Exh. 40 (ABBOTT_TRICOR00236508-526, 514) ;

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Moreover, Defendants did not and could not reasonably believe that they could properly assert a claim of infringement of their process patents because those patents were unenforceable. Abbott listed Defendants' fenofibrate-related patents in the Orange Book in order to position itself to invoke statutory 30-Month Stays of FDA approval of generic formulations. Defendants maintained and aggressively litigated patent infringement lawsuits against generic manufacturers without hope of prevailing on the merits, solely to stall generic competition and to complete their market switch. But for the wrongful and deceptive listing of the patents in the Orange Book and the subsequent infringement suits that gave rise to Hatch-Waxman Act stays, the FDA would have approved generic versions of TriCor much earlier. *See* End-Payor Complaint [D.I. 24] ¶¶ 81-85.

Defendants also engaged in the scorched-earth tactics of manipulating the pharmaceutical distribution infrastructure to insure the success of their product hopping. As a result, when generic manufacturers were eventually able to get their fenofibrate products to market, they were unable to market their products *as generics*. The National Drug Data File ("NDDF") is a widely accepted database provided by First Databank, Inc. that includes drug descriptive and pricing information with an extensive array of clinical decision-support modules. This electronic drug database encompasses every drug approved by the FDA, including generic alternatives. It is used throughout the healthcare industry. An NDDF listing is essential for a generic product to be marketed.

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REDACTED [17] With each new switch to a new version of TriCor, Defendants strategically removed the codes for the old versions from the NDDF, thus insuring that the branded drug code reference no longer existed for purposes of generic substitution laws or for purposes of health care providers' pharmaceutical benefit programs. For instance, after the codes were removed, Teva's generic fenofibrate capsule could not be marketed as a generic; Teva was forced to market the product as a brand – Lofibra – that could not take advantage of generic substitution laws or more favorable generic co-payment schedules from managed care plans' formularies.[18] Defendants also made slight dosage form changes to make substitution more difficult. REDACTED

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[17] McDonald Declaration Exh. 35 (ABBOTT_TRICOR00000739-764, 755); *see also id.*

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[18] *See* McDonald Declaration Exh. 41: REDACTED (ABBOTT_TRICOR00069502-516, 503)

id. at 512 REDACTED

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[19] McDonald Declaration Exh. 35 (ABBOTT_TRICOR00000752) (emphasis added). *see also id.* at 756 REDACTED

[20] McDonald Declaration Exh. 6: REDACTED (ABBOTT_TRICOR00000717-720, 718). *See also* Exh. 35 at ABBOTT_TRICOR00000756

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Without automatic substitution, pharmacists would be required to contact physicians in order to change a TriCor prescription to a fenofibrate product that is not AB-rated.

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C. Plaintiffs and Members of the Class Have Been and Continue To Be Harmed By Paying Substantial Overcharges for Fenofibrate Products.

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[21] McDonald Declaration Exh. 42 (ABBOTT_TRICOR00074957-973, 960).

[22] McDonald Declaration Exh. 33 at ABBOTT_TRICOR00090960.

[23] *See, e.g.*, McDonald Declaration Exh. 43 (ABBOTT_TRICOR00089733-757, 737)

REDACTED

[24] *See, e.g.*, McDonald Declaration Exh. 44 (ABBOTT_TRICOR00086863-864)

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Exh. 45 (ABBOTT_TRICOR00066593-608, 600)

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[25]

[25] McDonald Declaration Exh. 6 at ABBOTT_TRICOR00000718).

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Indeed, Defendants' foreclosure of generic fenofibrate products from the market has enabled them unlawfully to maintain a monopoly – REDACTED

REDACTED [27]

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Defendants' unlawful scheme has harmed Plaintiffs and all Class members and caused them to pay substantial overcharges for branded fenofibrate products.

IV. THE LEGAL STANDARD

"A party seeking class certification bears the burden of proving that the proposed class action satisfies the requirements of Rule 23." *In re Microcrystalline Cellulose Antitrust Litig.*, 218 F.R.D. 79, 82 (E.D. Pa. 2003). "It must be recalled, however, that Rule 23 and modern class action practice in the federal courts have their roots in equity, and this Court must exercise its discretion in ruling on a motion to certify." *In re Mercedes-Benz Antitrust Litig.*, 213 F.R.D. 180, 183 (D.N.J. 2003) (citations omitted). "In determining the propriety of a class action, the question is not whether the plaintiff or plaintiffs have stated a cause of action or will prevail on the merits, but rather whether the requirements of Rule 23 are met." *Mercedes-Benz*, 213 F.R.D. at 190 (quoting *Eisen v. Carlisle and Jacquelin*, 417 U.S. 156, 178 (1974)).[28]

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[26] *Id.* at ABBOTT_TRICOR00000719.

[27] McDonald Declaration Exh. 3 (ABBOTT_TRICOR0052020).

[28] *See also In re Cardizem CD Antitrust Litig.* ("*Cardizem (Class Certification)*"), 200 F.R.D. 326, 334 (E.D. Mich. 2001) (Rule 23 determination "is wholly procedural and has nothing to do with whether a plaintiff will ultimately prevail on the substantive merits of its claim.").

While "[t]he [c]ourt is not to conduct a preliminary inquiry into the merits of plaintiffs' case," *Mercedes-Benz*, 213 F.R.D. at 190, the Third Circuit has recognized the utility, and often necessity, of looking beyond the pleadings to determine whether the claims can be addressed on a class-wide basis. *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 168-69 (3d Cir. 2001). Accordingly, the Court can consider expert reports and factual support in the record. *Microcrystalline Cellulose*, 218 F.R.D. at 83.

Courts have long recognized the propriety of class certification in antitrust cases in general,[29] and in cases concerning pharmaceutical pricing in particular.[30] Because of the important role that class actions play in the private enforcement of litigants' rights, courts resolve doubts about whether a class should be certified in favor of certification. *Prudential*

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[29] *See, e.g., Amchem Prod., Inc. v. Windsor*, 521 U.S. 591, 625 (1997); *In re Linerboard Antitrust Litig.*, 305 F.3d 145 (3d Cir. 2002) (upholding class certification); *Microcrystalline Cellulose*, 218 F.R.D. 79 (granting class certification); *Mercedes-Benz*, 213 F.R.D. 180 (same); *In re Flat Glass Antitrust Litig.*, 191 F.R.D. 472 (W.D. Pa. 1999) (same); *In re Plastic Cutlery Antitrust Litig.*, No. 96-CV-728, 1998 WL 135703, at *5 (E.D. Pa. Mar. 20, 1998) (same); *Lumco Indus., Inc. v. Jeld-Wen, Inc.*, 171 F.R.D. 168 (E.D. Pa. 1997) (same).

[30] *See, e.g., International Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co.*, Docket No. A-0450-05T1, 2006 WL 827285 (N.J. Super. A.D. Mar. 31, 2006) (nationwide class of third-party payors of Vioxx); *Ferrell v. Wyeth-Ayerst Labs., Inc.*, Case No. C-1-01-447 (S.D. Ohio June 30, 2004) (order granting motion for class certification); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260 (D. Mass. 2004); *In re Terazosin Hydrochloride Antitrust Litig.* ("*Hytrin*"), 220 F.R.D. 672 (S.D. Fla. 2004); *Cardizem (Class Certification)*, 200 F.R.D. 326; *In re Synthroid Marketing Litig.*, 188 F.R.D. 287, 295 (N.D. Ill. 1999); *In re Antibiotics Antitrust Actions*, 333 F. Supp. 278 (S.D.N.Y. 1971); *Clark v. TAP Pharm. Prods., Inc.*, 798 N.E.2d 123 (Ill. App. 2003); *In re Pennsylvania Baycol Third-Party Payor Litig.*, No. 1874 Sept. Term 2001, 2005 WL 852135 (Phila. C.C.P. Apr. 4, 2005) (nationwide third-party payor class).

The above list does not include cases where class certification was granted as to settlement classes, meaning that the court determined that the class met all the conditions of Rule 23(a) and (b)(3) except manageability at trial. *See In re Lupron Marketing and Sales Practices Litig.*, 228 F.R.D. 75 (D. Mass. 2005); *In re Augmentin Antitrust Litig.*, No. 2-cv-442 (E.D. Va. Jan. 10, 2005); *In re Buspirone Antitrust Litig.*, MDL Docket No. 1413 (S.D.N.Y. Nov. 18,2003); *In re Lorazepam & Clorazepate Antitrust Litig.* ("*Lorazepam II*"), 205 F.R.D. 369 (D.D.C. 2002); *Nichols v. SmithKline Beecham Corp.*, C.A. No. 00-6222, 2005 WL 950616, at *7 (E.D. Pa. Apr. 22, 2005); *Warfarin Sodium II*, 212 F.R.D. at 346-52; *In re Cardizem CD Antitrust Litig.*, 218 F.R.D. 508, 517-519 (E.D. Mich. 2003); *In re Relafen Antitrust Litig.*, 231 F.R.D. 52, 74-76 (D. Mass. 2005); *In re Remeron End-Payor Antitrust Litig.*, No. 02-2007, 04-5126, 2005 WL 2230314, at * 8 (D.N.J. Sept. 13, 2005).

Sales Practices I, 962 F. Supp. 450; *Eisenberg v. Gagnon*, 766 F.2d 770, 785 (3d Cir. 1985); *Cardizem (Class Certification)*, 200 F.R.D. 326, 334.

V. ARGUMENT

A. The End-Payor Plaintiff Class Satisfies The Requirements of Rule 23(a).

Rule 23(a) states that a class action may be certified

> only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

As set forth herein, Plaintiffs satisfy all of the requirements of Rule 23(a).

First, the proposed Class is sufficiently numerous. Independent data shows that tens of millions of prescriptions for TriCor were dispensed in the last several years, **REDACTED** [31] Thus, the numerosity requirement is easily satisfied. *See, e.g., Warfarin Sodium II*, 212 F.R.D. at 247; *Remeron*, 2005 WL 2230314, at *8; *Cardizem (Class Certification)*, 200 F.R.D. at 335.

Second, this litigation involves numerous issues of law and fact that are common to the Class. *See* End-Payor Complaint [D.I.24] ¶101 (enumerating questions common to the Class). Rule 23(a)(2) has been characterized as requirement "easily met." *Baby Neal v. Casey*, 43 F.3d 48, 56 (3d Cir. 1994). Because the commonality requirement is incorporated within Rule 23(b)(3)'s predominance requirement, the Third Circuit analyzes the two factors together. *See Warfarin Sodium III*, 391 F.3d at 528. As addressed in Section IV. C., *infra*, common questions are the predominant focus of the litigation.

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[31] *See* McDonald Declaration Exhs. 46, 47 (ABBOTT_TRICOR00095611).

Third, End-Payor Plaintiffs' claims are typical of the entire Class. Rule 23(a)(3)'s "typicality requirement is designed to align the interests of the class and the class representatives so that the latter will work to benefit the entire class through the pursuit of their own goals. However, typicality ... does not require that all putative class members share identical claims." *In re Molson Coors Brewing Co. Sec. Litig.*, 233 F.R.D. 147, 152 (D. Del. 2005) (Jordan, J.) (quoting *Warfarin Sodium III*, 391 F.3d at 531-32). "Indeed, even relatively pronounced factual differences will generally not preclude a finding of typicality where there is a strong similarity of legal theories." *Id.* (quoting *Baby Neal*, 43 F.3d at 58); *see also In re Lorazepam & Clorazepate Antitrust Litig.* ("*Lorazepam I*"), 202 F.R.D. 12, 27 (D.D.C. 2001) (named plaintiffs not required to be "clones" of each other or other class members).

The focus must be on the defendant's behavior, not that of the plaintiffs. *Prudential Sales Practices II*, 148 F.3d at 311; *Newton*, 259 F.3d at 183-84. In *Prudential Sales Practices II*, the Third Circuit upheld certification because although the claims and injuries of class members differed depending on the sales tactics used, the named plaintiffs and absent class members "all have claims arising from the fraudulent scheme perpetrated by Prudential. That overarching scheme is the linchpin of the [complaint . . . and] provides an appropriate basis for a finding of typicality." 148 F.3d at 311-12.

Here, Plaintiffs and all Class members were harmed by Defendants' unlawful monopolistic conduct and unfair trade practices that foreclosed competition from generic fenofibrate products. Thus, their claims are typical of the claims of all Class members. *See, e.g.*, *Remeron*, 2005 WL 2230314, at *8 (typicality satisfied: claims were based on defendants' alleged improper listing and late listing of patent in the Orange Book, fraud on the PTO, and filing of allegedly baseless patent infringement lawsuits against generic manufacturers).

Finally, End-Payor Plaintiffs will adequately represent the Class. "[T]he adequacy inquiry under Rule 23 has two components designed to ensure that absentees' interests are fully pursued. First, the adequacy inquiry tests the qualifications of the counsel to represent the class. Second, it seeks to uncover conflicts of interest between named parties and the class they seek to represent." *Molson*, 233 F.R.D. at 153 (quoting *Warfarin Sodium III*, 391 F.3d at 532). Here, Plaintiffs have selected counsel with considerable experience in pharmaceutical antitrust class actions and complex litigation.[32] Moreover, the presence of common questions of fact or law and the typicality of Plaintiffs' claims establishes the coincidence of Plaintiffs' interests with those of the rest of the Class. Plaintiffs do not have any interests relative to the subject matter of the suit that are antagonistic to the Class. Any differences between consumers and TPPs relate solely to the allocation of class damages recovered, and numerous courts have certified indirect purchaser classes including both consumers and TPPs.[33] In sum, the experience of Plaintiffs' counsel and the commitment of Plaintiffs to the vigorous prosecution of this action should leave no doubt that Plaintiffs are adequate class representatives in satisfaction of Rule 23(a)(4).

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[32] *See* Declaration of Patrick E. Cafferty (the "Cafferty Declaration"), submitted contemporaneously herewith in support of End-Payor Plaintiffs' motion for appointment of class counsel pursuant to Fed. R. Civ. P. 23(g), at ¶¶ 4-7.

[33] *See, e.g., Remeron*, 2005 WL 2230314, at *11 ("The central issues in this case are critical to the claims of both groups."); *Cardizem* (*Class Certification*), 200 F.R.D. at 337 (rejecting defendants' contention that Aetna's interests as a TPP may conflict with the interests of consumers); *Lorazepam II*, 205 F.R.D. at 389-90 (rejecting assertion of conflict arising from joint representation of consumers and TPPs interests and approving the class action settlements); *see also Sebo v. Rubenstein*, 188 F.R.D. 310, 315 (N.D. Ill. 1999) ("The possibility that conspirators have spread increased costs among several parties should not be used to bar a class action suit, which is a particularly appropriate vehicle for such a situation."). *See also Warfarin Sodium II*, 212 F.R.D. at 250 (potential conflicts between consumers and TPPs resolved via allocation counsel mechanism); *Relafen*, 231 F.R.D. at 74-76. Here, Co-Lead Counsel for End-Payor Plaintiffs have designated separate consumer and TPP allocation counsel. *See* Cafferty Declaration ¶ 9.

B. The End-Payor Class Satisfies The Requirements of Rule 23(b)(2).

A class may be certified when the Rule 23(a) requirements have been met and

> the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole. . . .

Fed. R. Civ. P. 23(b)(2). This requirement is satisfied on a showing of a "significant threat of injury from an impending violation of the antitrust laws or from a contemporary violation likely to continue or recur." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 130 (1969). *See also In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493, 516 (S.D.N.Y. 1996) (a class should be certified under Rule 23(b)(2) "where declaratory or injunctive relief is an important aspect of the overall relief sought.").

Indirect purchasers have standing to seek injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26. *See In re New Motor Vehicles Canadian Export Antitrust Litig.*, MDL No. 1532, 2006 WL 623591 (D. Me. Mar. 10, 2006) (certifying nationwide indirect purchaser class under Rule 23(b)(2)). Efforts to suppress generic competition to brand-name drugs are aimed at increasing prices to end-payors. *See Warfarin Sodium I*, 214 F.3d at 402 ("Unless enjoined, DuPont's unlawful conduct will continue unchecked and the class will continue to bear the financial brunt of the antitrust violations."). Accordingly, End-Payor Plaintiffs seek to enjoin Defendants' continuing unlawful acts of monopolization and attempted monopolization in the market for fenofibrate products – anticompetitive conduct that violates Section 2 of the Sherman Act and continues to harm Class members.

If Plaintiffs prove their case, they are entitled to an injunction preventing Defendants from engaging in the same unlawful techniques to acquire and maintain a future fenofibrate

monopoly. *See Davis v. Southern Bell Tel. & Tel. Co.*, No. 89-2839, 1993 WL 593999, at *7 (S.D. Fla. Dec. 23, 1993). Because an injunction is an important component of the relief Plaintiffs seek, the Court should certify the Class pursuant to Rule 23(b)(2) for purposes of pursuing Count I only. *See NASDAQ*, 169 F.R.D. at 515 ("Courts have certified antitrust class actions both under Rule 23(b)(2) and (b)(3) if the requirements of each rule are satisfied."). *See also In re Visa Check/Mastermoney Antitrust Litig.*, 192 F.R.D. 68, 88-89 (E.D.N.Y. 2000) (certifying a class action under Rule 23(b)(3) and Rule 23(b)(2) because the plaintiffs sought "highly significant injunctive relief"), *aff'd*, 280 F.3d 124 (2d Cir. 2001).

C. The End-Payor Class Satisfies the Requirements of Rule 23(b)(3).

Rule 23(b)(3) permits the maintenance of a class action if "the court finds [a] that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and [b] that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Both requirements are satisfied with respect to End-Payor Complaint Counts II-V.

1. Common Questions of Law and Fact are Predominant.

"The Rule 23(b)(3) predominance inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Amchem Prod., Inc.* 521 U.S. at 623; *see also Newton*, 259 F.3d at 186-87 (citing *Amchem*). It "is a test readily met in certain cases alleging consumer or securities fraud or violations of the antitrust laws." *Amchem*, 521 U.S. at 625. *See Prudential Sales Practices II*, 148 F.3d at 314; *In re Buspirone Patent Litig.*, 210 F.R.D. 43, 58 (S.D.N.Y. 2002). Where, as here, common questions predominate regarding liability, courts generally find the predominance requirement to be satisfied even if individual damages issues remain. *See Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 456 (3d Cir. 1977) ("[T]he

necessity for calculation of damages on an individual basis should not preclude class determination when the common issues which determine liability predominate."); *Eisenberg*, 766 F.2d at 786.[34]

A review of Plaintiffs' claims in Counts II-V demonstrates that the questions common to class members easily predominate over any questions affecting only individual members. Count II asserts violations of state laws analogous to Section 2 of the Sherman Act. "Under both federal and state law, the essential elements of a private antitrust action are the same . . . ." *Relafen*, 221 F.R.D. at 275. In Count III, Plaintiffs assert claims for unjust enrichment. All jurisdictions recognize the basic equitable principle that "[a] person who is unjustly enriched at the expense of another is liable in restitution to the other." Restatement (Third) of Restitution & Unjust Enrichment, § 1 (1937). Finally, in Counts IV and V, Plaintiffs assert violations of state consumer protection statutes. Every state has adopted a consumer protection statute prohibiting unfair or deceptive practices, most of which are modeled after Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1), and/or incorporate language requiring courts to defer to federal and administrative interpretations of Section 5 of the FTC Act when interpreting their own statutes. Differences in state law do not in themselves preclude certification because numerous courts have recognized that such differences can be appropriately managed when the core facts are common to the class. *See Prudential Sales Practices II*, 148 F.3d at 315 ("Courts have expressed a willingness to certify nationwide classes on the ground that relatively minor differences in

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[34] *See also, e.g., Linerboard*, 305 F.3d at 151 (""[A]n individual plaintiff could prove fact of damage simply by proving that the free market prices would be lower than the prices paid and that he made some purchases at the higher price[,]' *Bogosian*, 561 F.2d at 455, this would be a demonstration of the laws of supply and demand at work.").

state law could be overcome at trial by grouping similar state laws together and applying them as a unit."); *Bussie v. Allmerica Fin. Corp.*, 50 F. Supp. 2d 59, 71 (D. Mass. 1999). Any difficulties that arise during discovery, pretrial or trial "may be effectively managed through traditional procedural techniques such as special interrogatories, special verdict forms, subclasses, or sequenced trial phases." *Prudential Sales Practices I*, 962 F. Supp. at 525.

(a) Common Questions Of Law And Fact Are Predominant With Respect To Plaintiffs' Antitrust Claims.

In Count II, brought on behalf of Class members in the Indirect Purchaser States,[35] Plaintiffs allege that Defendants monopolized the market for fenofibrate products in violation of state antitrust and consumer fraud statutes that mirror Section 2 of the Sherman Act. With certain exceptions,[36] the state antitrust statutes at issue are interpreted in accordance with federal antitrust law pursuant either to an express harmonization provision or judicial decision.[37] "To prevail, a civil antitrust plaintiff must establish (1) a violation of the antitrust laws, (2) the fact of antitrust injury or 'impact' on the plaintiffs, and (3) what

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[35] The Indirect Purchaser States included in Count II are: Arizona, California, the District of Columbia, Florida, Iowa, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Vermont, West Virginia and Wisconsin. *See* End-Payor Complaint [D.I. 24] ¶¶ 10, 112. New Jersey (referenced in ¶ 10 and 112(o)) is not included for purposes of this motion.

[36] Indirect purchasers lack standing to sue for damages under the federal antitrust laws, *see Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), but the Supreme Court has expressly left it to the states to determine if state laws should permit indirect purchasers to bring suit for antitrust damages. *See California v. ARC Am. Corp.*, 490 U.S. 93 (1989). *See also* McDonald Declaration Exh. 48 (Tab A): *Twenty-Three Jurisdiction Survey of Statutory Claims for Indirect Purchaser Recovery of Damages for Antitrust Injuries.*

[37] *See* McDonald Declaration Exh. 48 (Tab A); *see also In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 906 (6th Cir. 2003) ("It is undisputed that the state antitrust statutes at issue either follow federal Sherman Act precedent or find federal case law persuasive."); *United States v. Microsoft Corp.*, 87 F. Supp. 2d 30, 54 n. 7 (D.D.C. 2000) ("The facts proving that Microsoft unlawfully maintained its monopoly power in violation of § 2 of the Sherman Act are sufficient to meet analogous elements of causes of action arising under the laws of each plaintiff state.") (footnote omitted), *aff'd in part, rev'd in part on other grounds*, 253 F.3d 43 (D.C. Cir. 2001).

damages were sustained." *Mercedes-Benz*, 213 F.R.D. at 186-87 (citing *Danny Kresky Enters. Corp. v. Magid*, 716 F.2d 206, 209-10 (3d Cir. 1983)).

(i) Violation of State Antitrust Laws Focuses Exclusively On Defendants' Conduct.

"[A]ntitrust actions involving common questions of liability for monopolization ... have frequently been held to predominate for the preliminary stage of class certification." *Remeron*, 2005 WL 2230314, at *11 (quoting *Lorazepam I*, 202 F.R.D. at 29). Plaintiffs will show that Defendants: (1) possessed monopoly power in the relevant market;[38] and (2) willfully acquired, maintained or used that power by anticompetitive or exclusionary means. *Lorazepam I*, 202 F.R.D. at 29 n.11; *see also Cardizem* (*Class Certification*), 200 F.R.D. at 331 (addressing the Michigan Antitrust Reform Act). Monopoly power has been defined as the power to control or exclude competition, and its existence may be inferred when the defendant maintains a predominant share of the market. *See United States v. Grinnell*, 384 U.S. 563, 571 (1966).

As in *Linerboard*, 305 F.3d at 163, "common issues ... predominate here because the inquiry necessarily focuses on defendants' conduct, that is, what defendants did rather than what plaintiffs did." (citation omitted). *See also Warfarin Sodium III*, 391 F.3d at 528 ("[P]roof of liability for DuPont's conduct under § 2 of the Sherman Act . . . depends on evidence which is common to the class members"). Indeed, "[t]he common questions of law, the elements of the monopolization claim fully enumerated, ... dwarf, rather than merely

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[38] The relevant market in this case is the market for fenofibrate products, which consists of TriCor products and generic bioequivalent versions of TriCor® products. End-Payor Complaint ¶ 24; *cf. Cardizem* (*Class Certification*), 200 F.R.D. at 310-11. **REDACTED** McDonald Declaration Exh. 3 (ABBOTT_TRICOR00052020).

predominate over, any individual questions." *Remeron*, 2005 WL 2230314, at *12 (quoting *Sollenbarger v. Mountain States Tel. & Tel. Co.*, 121 F.R.D. 417, 427 (D.N.M. 1988)).[39] The claims of all Class members arise from the exact same operative facts — Defendants' scheme to "stymie" consumer access to generic fenofibrate products — giving rise to substantially identical legal claims.

(ii) Antitrust Impact Is Susceptible To Class-Wide Proof.

At the class certification stage, "the Court need not concern itself with whether Plaintiffs *can* prove their allegations regarding common impact; the Court need only assure itself that Plaintiffs' *attempt* to prove their allegations will predominantly involve common issues of fact and law." *Linerboard*, 305 F.3d at 152 (emphasis added; quoting *Lumco Indus.*, 171 F.R.D. at 174).[40] "Plaintiffs need only make a threshold showing that the element of impact will predominantly involve generalized issues of proof, rather than questions which are particular to each member of the plaintiff class." *Id.* (citations omitted).

As in cases such as *Remeron*, *Warfarin Sodium*, *Relafen* and *Cardizem*, end-payors here were harmed by an anticompetitive scheme that blocked or delayed the market entry of

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[39] *See also Visa Check/Mastermoney*, 192 F.R.D. at 88 (elements of Section 2 claims "focus on the defendants' conduct and its effects on the relevant markets, factors that will not vary from plaintiff to plaintiff."); *Lorazepam I*, 202 F.R.D. at 29 (monopolization claim relates "solely to Defendants' conduct, and as such proof of these issues will not vary among class members") (citation omitted); *Robbins v. Manor Care, Inc.*, 172 F.R.D. 330, 337 (N.D. Ill. 1997) ("The question of whether Manor Care engaged in a 'willful acquisition' of monopoly power is ... common to all members of the class because of its susceptibility to common proof or disproof."); *Davis*, 1993 WL 593999, at *9 (common issues concerning monopolization and attempted monopolization "predominate in both number and complexity over the issues requiring individual proof").

[40] *See also Panache Broad. of Pennsylvania, Inc. v. Richardson Elec., Ltd.*, No. 90C6400, 1999 WL 342392, at *7 (N.D. Ill. May 14, 1999) ("the Court's research reveals no authority holding that Rule 23(b)(3) mandates a specific methodology for proving harmful impact prior to class certification"); *see also NASDAQ*, 169 F.R.D. at 521.

generic bioequivalents to a brand-name drug. This presents an attractive opportunity for a "yardstick" analysis, among others, to determine the "but for" competitive price for fenofibrate products that would have prevailed absent the antitrust violation.[41] *See* King Report ¶¶ 47-48 & Figure 3 (addressing potential yardsticks for measuring TriCor's price, revenue and market share erosion following the entry of generic competitors, **REDACTED** [42] *See Cardizem (Class Certification)*, 200 F.R.D. at 344 (certifying indirect purchaser class using "bottom across" approach to determine "but for" price of a brand-name drug in pharmaceutical antitrust case: "'Bottom across' means that the overcharge is determined by examining the price differential between the generic and the brand drug at the retail level only. Thus, there will be no need to review 'pass-through' variations.") (citing Roger D. Blair and Jeffrey L. Harrison, *Reexamining the Role of Illinois Brick in Modern Antitrust Standing Analysis*, 68 Geo. Wash. L. Rev. 1, 29 (1999)).[43]

Dr. King demonstrates that methodologies are available, **REDACTED** **REDACTED** , to demonstrate the impact of true

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[41] *See IP & Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, Vol 1 § 6.3, p.6-29 (Aspen Pub. 2005 Supp.) ("[T]he economic defenses of the *[Illinois Brick]* indirect purchaser rule rested on the assumption that the difficulty of computing pass-on justified the rule. In fact, however, computing the indirect purchaser's overcharge need not — and ordinarily does not — involve any computation of pass-on. In the typical case overcharge damages are measured by either the 'yardstick' method or the 'before-and-after' method ... and neither requires computation of the pass-on.").

[42] *See also Hytrin*, 220 F.R.D. at 697 ("Defendants [including Abbott] used the same data and a substantially similar methodology as that used by Indirect Purchaser Plaintiffs here to forecast the economic effects of generic competition for Hytrin. Other courts have found such generalized evidence of impact to be sufficient for class certification purposes.") (citing *Cardizem (Class Certification)*, 200 F.R.D. at 341).

[43] *See also Linerboard*, 305 F.3d at 153 (upholding class certification: plaintiffs' expert "presented two possible means of assessing impact on a class-wide basis--multiple regression analysis, and the benchmark or yardstick approach, which he described as methods of showing 'an antitrust impact by generalized proof.'"); *Plastic Cutlery*, 1998 WL 135703, at *7; *Flat Glass*, 191 F.R.D. at 485-486 (identifying multiple regression analysis as a method of proving impact).

generic competition in the "but for" world. *See* King Report ¶¶ 36-48. Generic drugs are considerably less expensive than brand-name drugs and their introduction leads to a significant erosion of branded-sales and reduction in the retail prices paid for the pharmaceutical, whether branded or generic. *Id.* ¶¶ 41-44. Thus, all end-payor Class members were harmed when they paid for more expensive brand-name fenofibrate products in the absence of substitutable generic versions of TriCor. *Id.* ¶ 66. Indeed, if End-Payor Plaintiffs demonstrate that Defendants unlawfully exercised monopoly power in the relevant market, the jury could *infer* that Plaintiffs and all Class members were damaged. *See Stephenson v. Bell Atlantic Corp.*, 177 F.R.D. 279, 287, 290 (D.N.J. 1997); *Davis*, 1993 WL 593999, at *6. Moreover, that some Class members may have theoretically been able to avoid injury is not enough to defeat class certification. *See Cardizem* (*Class Certification*), 200 F.R.D. at 346 ("That Plaintiffs may be unable to establish injury as to a few class members will not defeat class certification where they show widespread injury to the class.").[44]

Plaintiffs expect that Defendants will counter Dr. King's Report with an expert report of their own. Merely framing a "battle of experts," however, is not enough to preclude class certification. Whether or not Plaintiffs will ultimately succeed in proving impact on a class-wide basis is not before the Court at this time. *See Mercedes-Benz*, 213 F.R.D. at 190 (plaintiffs' economic expert "need not establish now that there is class-wide antitrust impact. Nor need he establish that plaintiffs' now have, in hand, all of the common evidence necessary to establish class-wide impact. Such a requirement would convert a class

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[44] *See also Davis*, 1993 WL 593999, at *6 ("[A]ll of the class representatives paid monopolistic prices for IWMS at some time and therefore suffered exactly the same type of injury as the absent class members.").

certification motion under Rule 23 into a summary judgment motion under Rule 56.") (citation omitted); *accord Disposable Contact Lens*, 170 F.R.D. 524, 531 (M.D. Fla. 1996); *Visa Check/Mastermoney*, 192 F.R.D. at 79. With the benefit of Dr. King's Report, Plaintiffs have made the "threshold showing" necessary to demonstrate that impact can be established by common proof. *See Linerboard*, 305 F.3d at 152.

(iii) Methodologies Allow For The Calculation Of Aggregate Damages to the Class.

Economic damages in pricing cases may be established by proving class-wide aggregate damages. *Boeing Co. v. Van Gemert*, 444 U.S. 472, 475-76 (1980); *Linerboard*, 305 F.3d at 155-58; *Prudential Sales Practices I*, 962 F. Supp. at 517. As the court in *Cardizem* (*Class Certification*) held, "[c]hallenges that such aggregate proof affects substantive law and otherwise violates the defendant's due process or jury trial rights to contest each member's claim individually, will not withstand analysis." 200 F.R.D. at 350 (quoting 2 Newberg on Class Actions, § 10.05 at 10-8 (3d ed. 1992)). Damages "may be determined on a class-wide, or aggregate, basis . . . where the computerized records of the particular industry, supplemented by claims forms, provide a means to distribute damages to injured class members in the amount of their respective damages." *NASDAQ*, 169 F.R.D. at 526; *accord*, *Lorazepam I*, 202 F.R.D. at 130.

Once aggregate damages are ascertained, a mechanism can easily be set up to calculate damages due to individual class members.[45] Courts that have dealt with damages-

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[45] *See, e.g., In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 141 (2d Cir. 2001) (collecting cases that describe management tools available to address individualized damages issues that might arise in a class action). In any event, the case law is clear that individual questions concerning damages should not preclude class certification where there are common liability issues.

(continued . . .)

related issues in pharmaceutical litigation have found that the industry is particularly suited to damages calculations that can be computed "according to some formula, statistical analysis, or other easy or essentially mechanical methods." *Klay v. Humana, Inc.*, 382 F.3d 1241, 1260 (11th Cir. 2004), *cert denied, sub nom., UnitedHealth Group, Inc.*, 543 U.S. 1081 (2005). *See also Bogosian*, 561 F.2d at 456 ("[T]he necessity for calculation of damages on an individual basis should not preclude class determination when the common issues which determine liability predominate."); *Warfarin Sodium II*, 212 F.R.D. at 249 ("[T]he need for individual damages calculations does not defeat predominance and class certification."); *Cardizem (Class Certification)*, 200 F.R.D. 326, 345 (E.D. Mich. 2001) ("defendants' attempt to characterize the market as too complex for common proof of injury is not unique").

Indeed, it is an "extreme case[ ] in which calculation of damages may present such an intolerable burden that it renders class certification inappropriate," and that "such cases rarely, if ever, come along." *In re Initial Public Offering Sec. Litig.*, 227 F.R.D. 65, 116 (S.D.N.Y. 2004) (quoting *Klay*, 382 F.3d 1241). While determining class damages may be "a laborious and time consuming task," it is superior to the "staggeringly inefficient" approach of requiring each class member to prove adverse impact in individual proceedings, which "would provide countless opportunities for juries to render inconsistent verdicts" and present many individual class members with a formidable, if not complete, cost barrier to recovery. *Id.* at 117.

(… continued)
See Gavron v. Blinder Robinson & Co., 115 F.R.D. 318, 325 (E.D. Pa. 1987) (potential mechanics of computing damages suffered by the individual class members does not bar class certification); *Wolgin v. Magic Market Corp.*, 82 F.R.D. 168, 176 (E.D. Pa. 1979) ("[T]he 'overwhelming weight of authority' holds that the need for individual damages calculations does not diminish the appropriateness of class action certification where common questions as to liability predominate.").

In this case, Dr. King has offered an opinion concerning "yardstick" models available to calculate overcharge damages on an aggregate basis. King Report ¶¶ 52-60.[46] These models compare actual prices and quantities that would have existed in a "but for" world without the alleged illegal conduct. To establish the prices and quantities in the absence of anticompetitive activities, the models use pricing and quantity data for products in a comparison market not affected by illegal behavior. These "yardsticks" are then used to estimate what Class members would have spent on brand name TriCor and generic fenofibrtate absent the unlawful conduct. *Id.* ¶ 52.[47]

(b) Plaintiffs' Unjust Enrichment Claims Give Rise to Predominant Common Questions.

In Count III, Plaintiffs assert claims for unjust enrichment. All jurisdictions recognize the basic equitable principle that "[a] person who is unjustly enriched at the expense of another is liable in restitution to the other." *Restatement (Third) of Restitution & Unjust Enrichment*, § 1 (1937).[48] "Generally speaking, in order to state a claim for unjust enrichment, a plaintiff must allege (1) at plaintiff's expense (2) defendant received benefit

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[46] *Cf. Disposable Contact Lens*, 170 F.R.D. at 531 (plaintiff only need show a "colorable method" of proving the class's impact and damages at trial); *NASDAQ*, 169 F.R.D. at 522 (same); *In re Commercial Tissue Prod. Antitrust Litig.*, 183 F.R.D. 589, 596 (N.D. Fla. 1998) (same).

[47] *Cf. Lumco Indus.*, 171 F.R.D. at 174 ("At this point, . . . Plaintiffs are not required to come forward with more specific formulas for calculating damages. Professor Asher's methodologies appear both logical and feasible. Similar methods have been proposed and accepted by courts in other class actions."); *Stephenson*, 177 F.R.D. at 288 ("Plaintiffs intend to calculate damages on a class-wide basis by employing the 'competitive benchmark' method. This method involves the use of econometric techniques to determine the IWMS prices that would have prevailed in a fully competitive market. According to plaintiffs, once the competitive prices are established, calculating damages on an individual basis becomes mechanical and thus will not overwhelm the various issues common to their antitrust claims.").

[48] *See* McDonald Declaration Exh. 48 (Tab B): *Fifty-One Jurisdiction Survey of Unjust Enrichment Law*. *See also Hytrin*, 220 F.R.D. at 692 (granting certification of proposed multi-state class because "[t]he standards for evaluating each of the various states classes' unjust enrichment claims are virtually identical.").

(3) under circumstances that would make it unjust for defendant to retain benefit without paying for it. *Restatement of Restitution* § 1 (1937)." *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 544 (D.N.J. 2004) (addressing multistate unjust enrichment claims). These elements are common throughout the country. *Singer v. AT&T Corp.*, 185 F.R.D. 681, 692 (S.D. Fla. 1998) (unjust enrichment is a "universally recognized cause[ ] of action that [is] materially the same throughout the United States"); *see also Warfarin Sodium III*, 391 F.3d 516 (3d Cir. 2004) (upholding certification of nationwide settlement class for unjust enrichment claims, among others); *Hill v. Galaxy Telecomm., L.P.*, 184 F.R.D. 82 (N.D. Miss. 1999) (certifying 15-state unjust enrichment class).

Plaintiffs will prove these elements predominantly with class-wide evidence. The second and third elements focus on Defendants' knowledge and conduct, so that the relevant evidence is the same for all Class members. The first element simply requires Plaintiffs to prove their purchases of TriCor, which permitted Defendants to earn extra profits and receive overcharges.

The remedy for unjust enrichment is restitution and is measured as the value of the benefit that the defendant unjustly retains. *See Restatement* § 1; *accord* D. Dobbs, Handbook of the Law of Remedies: Damages-Equity- Restitution 623-24 (1973). The restitution remedy, because it focuses on a defendant's gain and because it is uniformly available in all jurisdictions, is well-suited for multi-state class treatment, as federal courts have recognized. *See In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 668-671 (E.D. Mich. 2000); *Singer*, 185 F.R.D. at 692; *Hytrin*, 220 F.R.D. at 697.

Here, the benefits Defendants unjustly acquired and retained are the profits on sales of TriCor that would not have occurred had generic competition existed beginning in

February 2001. *Cf. Cardizem CD*, 105 F. Supp. 2d at 671. Measurement of the restitution remedy is common to the class because it is based on aggregate profits and overcharges received by Defendants. *See* King Report ¶¶ 61-64 (addressing standard methodology for estimating "but for" profits that Defendants would have earned absent the unlawful conduct). Thus, disgorgement of Defendants' ill-gotten gains is appropriate under the unjust enrichment laws of all jurisdictions, and the availability of class-wide evidence to prove violations of those laws satisfies Rule 23's predominance requirement. *See Cardizem* (*Class Certification*), 200 F.R.D. at 352 ("Plaintiffs' success or failure in proving this unjust enrichment claim will mean success or failure for the class as a whole; not individual class members.").[49]

(c) Common Issues Predominate With Respect to State Consumer Protection Law Violations.

As with Plaintiffs' antitrust and unjust enrichment claims, common questions are also predominant with respect to certification of the Class for purposes of pursuing consumer protection claims.[50] Every state and the District of Columbia has enacted consumer protection legislation. End-Payor Plaintiffs move for certification on behalf of TriCor end-payors in forty-two states and the District of Columbia, as follows.

While often referred to as "consumer fraud" acts, not all consumer protection statutes require deception. Some require only that the business practices at issue be, *e.g.*,

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[49] *See also Clark*, 798 N.E.2d at 132 (rejecting defendants' contention that unjust enrichment claims required "a physician-by-physician evaluation ... to determine why each physician decided to administer [the drug] Lupron.").

[50] *See Prudential Sales Practices II*, 148 F.3d at 315; *Warfarin Sodium II*, 212 F.R.D. at 248 & n.15; *see also Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1022-23 (9th Cir. 1998) (noting in the context of nationwide class claims that "the idiosyncratic differences between state consumer protection laws are not sufficiently substantive to predominate over the shared claims.")

"unfair" or "unconscionable." Notwithstanding this distinction, Defendants "overarching scheme" to thwart generic competition violates the consumer protection laws of virtually every state since it is both unfair and deceptive.[51]

Defendants intentionally misrepresented and omitted material facts in connection with their conduct before the PTO, in the sale or advertisement of TriCor, in the filing of fraudulently procured patents in the FDA's Orange Book, in the prosecution of "sham" patent infringement litigation for purposes of foreclosing generic entry, and in preventing or suppressing competition from generic versions of the drug by removing the NDDF codes of earlier versions of the brand name drug. Doctors, patients and TPPs were misled by Defendants into believing that they must purchase TriCor instead of generic versions of the discontinued forms of TriCor at a fraction of the price. End-Payor Complaint [D.I. 24] ¶ 119. Thus, Defendants' conduct violates virtually every state's consumer protection law because, in addition to being manifestly unfair, it is also deceptive.

The certification of consumer protection claims sought here is consistent with the multi-state class certified in *In re Pharmaceutical Industry Average Wholesale Price Litig.*, 230 F.R.D. 61 (D. Mass. 2005) ("*AWP I*") and 233 F.R.D. 229 (D. Mass. 2006) ("*AWP II*") (together, "*AWP*"). *AWP* involved allegations of fraud and deception concerning pharmaceutical manufacturers' pricing of branded-pharmaceuticals. On plaintiffs' motion for class certification, the court certified a nationwide class based on the consumer protection laws of forty-three jurisdictions (*i.e.*, pursuant to the consumer protection statutes

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[51] *See* McDonald Declaration Exh. 48 (Tab C): *Forty-Three Jurisdiction Survey of Consumer Protection Statutes.*

in all but the few states where the court believed there to be obstacles to consumer standing or class actions). *See AWP I*, 230 F.R.D. at 84 and *AWP II*, 233 F.R.D. at 230.

Critically, the *AWP* court found that slight variations in legal standards, such as scienter, causation and reliance, were unlikely to be material. *AWP I*, 230 F.R.D. at 85 ("different standards governing scienter do not present individual issues. . . . there is no indication that different definitions of reliance and causation will matter or cannot be resolved as a matter of law prior to trial"). The same logic applies here, where the suppression of generic competition has deprived all consumers of the option to purchase a generic fenofibrate product with a lower sales price and/or co-payment. Indeed, it applies with greater force here, as this case is far less complex. *See id.* at 230 (certifying plaintiff class of tens of millions of MediCare Part B Plan participants and involving scores of dosages of seventeen different drugs and more than a dozen defendants).

Moreover, any variation among the legal standards can be readily handled by appropriate instructions and questions to the jury. Jury instructions can be patterned to account for variations in state law and special verdict forms can be used to address those variations. In *In re General Motors Corp. Pick Up Truck Fuel Tank Prods. Liab. Litig.*, 55 F.3d 768 (3d Cir. 1995), the Third Circuit expressly approved such an approach, stating:

> In the *School Asbestos* case, 789 F.2d at 996, the panel asked counsel to analyze all the claims and defenses and write a report reflecting whether the differing claims and defenses evidence a small number of patterns that would be amenable to trial through a series of special verdicts. The plaintiffs came up with a demonstration that the claims and defenses were reducible to *four patterns*. That, in our view, *was sufficient to satisfy the commonality and typicality inquiries.*

55 F.3d at 799 n.22 (emphasis added).[52] Here too, common questions of law and fact predominate. Thus, proof of the violation of these statutes ought to proceed together in a common forum.

In sum, Defendants' anticompetitive scheme adversely affected everyone in the country who purchased or paid for fenofibrate products. The standards for the state law claims Plaintiffs assert are substantially similar in every subject jurisdiction, so that common factual and legal questions predominate over any individual issues that might arise. *See, e.g., Prudential Sales Practices I*, 962 F. Supp. at 525 ("Plaintiffs have demonstrated . . . that any state-by-state variations in the governing legal standards are manageable."); *Remeron*, 2005 WL 2230314 (certifying nationwide settlement class, including claims for violation of state antitrust and/or unfair competition statutes); *Mowbray v. Waste Mgm't Holdings, Inc.*, 189 F.R.D. 194, 199 (D. Mass. 1999) ("In order for certification to be proper under Rule 23(b), 'variations in state law [must not] swamp any common issues and defeat predominance.'") (citation omitted), *aff'd*, 208 F.3d 288 (1st Cir. 2000).[53] Accordingly, Plaintiffs have met their

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[52] The *Prudential Sales Practices* case provides additional support for certification of nationwide classes under multiple state laws. The district court approved a settlement valued as high as $2.1 billion on behalf of approximately eight million purchasers of insurance policies who claimed that they were misled through various deceptive sales practices. The district court specifically found that a class invoking laws of every state as to fraud and unjust enrichment was manageable. The district court and the Third Circuit approved a nationwide settlement class applying the laws of multiple states. Due to the presence of objectors to the settlement, all of the class certification issues were vigorously litigated, resulting in detailed opinions from both the trial and appellate courts. More importantly, the trial court evaluated and approved the proposed settlement class "*as if the case were to go to trial.*" *Prudential Sales Practices I*, 962 F. Supp. at 508 (emphasis added).

[53] Any differences in state laws should not be a basis for denying class certification at this stage. *See In re Kirschner Med. Corp. Sec. Litig.*, 139 F.R.D. 74, 84 (D. Md. 1991); *Maywalt v. Parker & Parsley Petroleum Co.*, 147 F.R.D. 51, 58 (S.D.N.Y. 1993); *Elliot v. ITT Corp.*, 150 F.R.D. 569, 579 (N.D. Ill. 1992); *In re LILCO Sec. Litig.*, 111 F.R.D. 663, 669 (E.D.N.Y. 1986); *Delgozzo v. Kenny*, 628 A.2d 1080, 1092 (N.J. App. Div. 1993). On a class certification motion, "the court need not anticipate that variance may exist between the laws of the various states involved, nor hypothesize about what state

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burden of demonstrating that their state law claims are based on substantially uniform principles. Thus, notwithstanding the potential application of multiple states' laws, common issues of law and fact remain the predominant focus of this litigation.

As an alternative to a single trial involving claims under all 43 consumer protection statutes, to increase manageability for trial purposes, the Court could also choose to limit class certification in the first instance to a particular group of states on an exemplar basis. *See Cardizem (Class Certification)*, 200 F.R.D. 326, 334 (E.D. Mich. 2001) (certifying exemplar class of Michigan Cardizem CD end-payors); *Relafen*, 221 F.R.D. 260 (certifying five state exemplar class of Relafen and nabumetone end-payers for purposes of litigation). In *Cardizem (Class Certification)* and *Relafen*, the initial decisions provided guidance in extending class certification to other states (and both cases subsequently certified nationwide classes for purposes of settlement).

2. A Class Action is Superior To Other Available Methods For The Adjudication Of This Controversy.

"The superiority requirement asks the court 'to balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods of adjudication'" *Prudential Sales Practices II*, 148 F.3d at 316. Clearly, "[m]ultiple lawsuits by the

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(... continued)
law will be relevant." *Somerville v. Major Exploration, Inc.*, 102 F.R.D. 500, 504-505 (S.D.N.Y. 1984). *See Synthroid*, 188 F.R.D. at 302 ("It is impossible at this stage of the proceeding, relying only on allegations in the class certification briefs, to resolve the choice of law issues."); *Hickey v. Great Western Mortg. Corp.*, 158 F.R.D. 603, 613 (N.D. Ill. 1994); *In re Crazy Eddie Sec. Litig.*, 135 F.R.D. 39, 41 (E.D.N.Y. 1991); *In re Pizza Time Theatre Sec. Litig.*, 112 F.R.D. 15, 18 (N.D. Cal. 1986); *Garner v. Healy*, 184 F.R.D. 598, 605 & n.8 (N.D. Ill. 1999); *Lobo Exploration Co. v. Amoco Prod. Co.*, 991 P.2d 1048, 1051 (Ok. Civ. App. 1999). Other courts have determined only which law is "likely" to be applied. *Randle v. Spectrum*, 129 F.R.D. 386, 393 (D. Mass. 1988); *Elkins v. Equitable Life Ins. Co. of Iowa*, C.A. No. 96-296, 1998 WL 133741, at *17 (M.D. Fla. Jan. 27, 1998). Accordingly, at this stage of the proceeding, it is not necessary for the Court to conclusively determine which substantive laws will ultimately govern Plaintiffs' claims.

large number of class members allegedly injured by Defendants' antitrust violations would be costly and inefficient." *Cardizem (Class Certification)*, 200 F.R.D. at 351 (citing *NASDAQ*, 169 F.R.D. at 527). In addition, as most Class members' individual claims are relatively small, it is unlikely that many would undertake the expense necessary to litigate these complex antitrust claims on an individual basis. Thus, a class action stands as the only practicable means by which Plaintiffs and the Class can litigate their antitrust claims against Defendants.

In certifying a class with state law claims, a trial court's major concern is whether the case is sufficiently manageable to be tried. However, manageability issues pose a barrier to class certification only where they create a situation in which the class action is less fair and efficient that other available adjudication techniques. *In re Vitamins Antitrust Litig.*, 209 F.R.D. 251, 270 (D. D.C. 2002); *In re Sugar Industry Antitrust Litig.*, 73 F.R.D. 322, 358 (E.D. Pa. 1976). "[M]ost courts hold that manageability difficulties cannot support denial of class certification when no other practical litigation alternative exists." *Prudential Sales Practices I*, 962 F. Supp. at 525. *See also Klay*, 382 F.3d at 1272 (concern as to manageability of a class action will rarely, if ever, be sufficient in itself to deny class certification); *In re Managed Care Litig.*, 209 F.R.D. 678, 692 (S.D. Fla. 2002) ("Courts are generally reluctant to deny class certification based on speculative problems with case management."), *aff'd in part, rev'd in part, sub nom., Klay v. Humana, Inc.*, 382 F.3d 1241 (11th Cir. 2004), *cert denied, sub nom., UnitedHealth Group, Inc.* 543 U.S. 1081 (2005).

Denial of class certification on the grounds of "vaguely perceived manageability obstacles" is strongly disfavored by courts and commentators as "counter to the policy behind Rule 23, and because that court [would be] discounting unduly its power and creativity in dealing with a class action flexibly as difficulties arise." *NASDAQ*, 169 F.R.D.

at 528; *Visa Check*, 280 F.3d at 140 (citing cases) (refusal to certify a class solely due to a lack of manageability is disfavored and "should be the exception rather than the rule"). What would be unmanageable would be 51 separate class actions and 51 separate trials – one for every jurisdiction. As the court in *In re Domestic Air Transp. Antitrust Litig.*, 137 F.R.D. 677 (N.D. Ga. 1991) aptly recognized in certifying a class of airline ticket purchasers, "[e]ither the case proceeds as a class action or it is over." 137 F.R.D. at 693-94; *accord In re Mercedes-Benz*, 213 F.R.D. at 191-92.

Plaintiffs are aware of no insurmountable management difficulties that will be encountered in the litigation on behalf of the Class. *Cf. Disposable Contact Lens*, 170 F.R.D. at 529, 533 (class of up to 18 million replacement contact lens purchasers); *Domestic Air Transp.*, 137 F.R.D. at 693 (certification of nationwide class of airline passengers numbering between 12 and 50 million members and involving up to 400 million transactions); *In re Compact Disc Minimum Advertised Price Antitrust Litig.*, 216 F.R.D. 197 (D. Me. 2005) (nationwide settlement class of retail purchasers certified, estimated as "millions of CD purchasers," where over 3,500,000 consumers filed claims). Therefore, Plaintiffs' motion for class certification should be granted in full.

VI. CONCLUSION

For all the foregoing reasons, End-Payor Plaintiffs respectfully request that this Court enter an Order certifying the Class pursuant to Rule 23(b)(2) and (b)(3), and certifying End-Payor Plaintiffs as representatives of the Class.

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